REMARKS

Applicant thanks the Examiner for the very thorough consideration given the present application.

Claims 1-12 are now present in this application. Claims 1, 2, 11 and 12 are independent. By this Amendment, claims 1-5 and 8-12 are amended. No new matter is involved.

Reconsideration of this application, as amended, is respectfully requested.

Restriction Requirement

Despite the fact that the RCE Amendment traverses the restriction requirement/holding of lack of unity of invention, the outstanding Office Action completely ignores these arguments, in direct contravention of the requirement in MPEP § 707.07(f) to treat the substance of Applicant's arguments and, thereby denying Applicant both procedural and substantive due process under the Administrative Procedures Act.

For this reason alone, the outstanding Office Action is patently incomplete and should be withdrawn and a new, non-final Office Action on the merits of all pending claims should be prepared and mailed.

Applicant continues to traverse the holding of lack of unity of invention/restriction requirement for the following reasons, and expects the Examiner to treat these arguments on their merits.

37 CFR § 1.475(b), which applies to this application, clearly, unequivocally and unmistakably states, in pertinent part, that a national stage application containing claims to different categories of invention *will be considered to have unity of invention* if the claims are drawn to only one of the following categories: (1) A product and a process specially adapted for the manufacture of said product.

The Office is bound to follow its own rules of practice, including this specific Rule of Practice during this national stage of Applicant's PCT Application.

Applicant respectfully submits that claims 9 and 10 are processes specially adapted for the manufacture of the product recited in claim 1 (and claim 2 with respect to claim 9).

In reply, the Office Action states that none of the method of manufacture steps are in fact specially adapted to the product at this time but, rather, are generic manufacturing claims to hollow fiber membrane assemblies.

Applicant respectfully disagrees for the following reasons.

Firstly, the PCT Administrative Instructions found in Annex B (Section AI of the MPEP), clearly state that a process shall be considered to be specially adapted for the manufacture of a product if the process inherently results in the claimed product with the technical relationship being presently between the claimed product and the claimed product, and "[T]he words 'specially adapted' are not intended to imply that the product could not also be manufactured by a different process."

Applicant respectfully submits that the processes recited in claims 8 and 9 inherently result the claimed product because claims 8 and 9 clearly recite "a method for manufacturing the external pressure type hollow type fiber membrane module according to claim 1 or claim 2." Accordingly, claims 8 and 9 processes which are specially adapted for the manufacture of the products of claims 8 and 9, respectively.

Accordingly, the Office is required to examine all pending claims, including claims 9 and 10.

Thus, withdrawal of the restriction requirement/lack of unity of invention holding, and reinstatement and examination of claims 9 and 10 along with claims 1-8 are respectfully requested.

Contingent Petition under 37 CFR §§ 1.181 and 1.144

Should the Examiner refuse to withdraw the restriction/holding of lack of unity of invention and refuse to treat claims 9 and 10 on their merits, then Applicant respectfully petitions the Commissioner under Rules 181 and 144 to order the Examiner to do so for the reasons presented above.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 1-8 and 12 are rejected under 35 U.S.C. § 112, second paragraph, for being

indefinite. The Office Action indicates that three instances of specific language lacks proper antecedent basis in these claims.

This rejection is respectfully traversed because, by this amendment. Applicant has amended the claims under rejection to overcome these rejections, without narrowing the scope of these portions of the claims being rejected.

Accordingly, reconsideration and withdrawal of this rejection are respectfully requested.

Rejections Under 35 U.S.C. §§ 102/103

Claims 1, 2 and 11-12 stand rejected under 35 U.S.C. § 102(b) as being anticipated by, or in the alternative, under 35 U.S.C. § 103(a) as being obvious over USP Re. 36,125 to Haworth et al. ("Haworth"). This rejection is respectfully traversed.

Because the rejection is based on 35 U.S.C. § 103, what is in issue in such a rejection is "the invention as a whole," not just a few features of the claimed invention. Under 35 U.S.C. §103, "[a] patent may not be obtained . . . if the differences between the subject matter sought to be patented and the prior art are such that the subject matter *as a whole* would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." The determination under § 103 is whether the claimed invention *as a whole* would have been obvious to a person of ordinary skill in the art at the time the invention was made. *See In re O'Farrell*, 853 F.2d 894, 902, 7 USPQ2d 1673, 1680 (Fed. Cir. 1988). In determining obviousness, the invention must be considered as a whole and the claims must be considered in their entirety. *See Medtronic, Inc. v. Cardiac Pacemakers. Inc.*, 721 F.2d 1563, 1567, 220 USPQ 97, 101 (Fed. Cir. 1983).

In rejecting claims under 35 U.S.C. § 103, it is incumbent on the Examiner to establish a factual basis to support the legal conclusion of obviousness. *See In re Fine*, 837 F.2d 1071, 1073, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). In doing so, the Examiner is expected to make the factual determinations set forth in *Graham v John Deere Co.*, 383 U.S. 1, 17, 148 USPQ 459, 467 (1966), and to provide a reason why one of ordinary skill in the pertinent art would have been led to modify the prior art or to combine prior art references to arrive at the claimed

invention. Such reason must stem from some teaching, suggestion or implication in the prior art as a whole or knowledge generally available to one having ordinary skill in the art. *See Uniroyal Inc. v. F-Wiley Corp.,* 837 F.2d 1044, 1051, 5 USPQ2d 1434, 1438 (Fed. Cir. 1988), *cert. denied,* 488 U.S. 825 (1988); *Ashland Oil, Inc. v Delta Resins & Refactories, Inc.*, 776 F.2d 281, 293, 227 USPQ 657, 664 (Fed. Cir. 1985), *cert. denied*, 475 U.S. 1017 (1986); *ACS Hospital Systems, Inc. v Montefiore Hospital*, 732 F.2d 1572, 1577, 221 USPQ 929, 933 (Fed. Cir. 1984). These showings by the Examiner are an essential part of complying with the burden of presenting a *prima facie* case of obviousness. *See In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443, 1444 (Fed. Cir. 1992). The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification. *See In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1783-84 (Fed. Cir. 1992). To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be suggested or taught by the prior art. *See In re Royka,* 490 F.2d 981, 180 USPQ 580 (CCPA 1970). All words in a claim must be considered in judging the patentability of that claim against the prior art. *See In re Wilson,* 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970).

A suggestion, teaching, or motivation to combine the prior art references is an "essential evidentiary component of an obviousness holding." *See C.R. Bard, Inc. v. M3 Sys. Inc.,* 157 F.3d 1340, 1352, 48 USPQ2d 1225, 1232 (Fed. Cir. 1998). This showing must be clear and particular, and broad conclusory statements about the teaching of multiple references, standing alone, are not "evidence." *See In re Dembiczak*, 175 F.3d 994 at 1000, 50 USPQ2d 1614 at 1617 (Fed. Cir. 1999).

Moreover, it is well settled that the Office must provide objective evidence of the basis used in a prior art rejection. A factual inquiry whether to modify a reference must be based on objective evidence of record, not merely conclusory statements of the Examiner. *See In re Lee*, 277 F.3d 1338, 1343, 61 USPQ2d 1430, 1433 (Fed. Cir. 2002).

Furthermore, during patent examination, the PTO bears the initial burden of presenting a *prima facie* case of unpatentability. *See In re Oetiker*, 977 F.2d 1443, 1445, 24 USPQ2d 1443,

1444 (Fed. Cir. 1992); *In re Piasecki*, 745 F.2d 1468, 1472, 223 USPQ 785788 (Fed. Cir. 1984). If the PTO fails to meet this burden, then the Applicant is entitled to the patent. Only when a *prima facie* case is made, the burden shifts to the Applicant to come forward to rebut such a case.

Rejections on obviousness grounds cannot be sustained by mere conclusory statements; instead there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness:" *In re Kahn*, 441 F.3d 977,988(Fed. Cir. 2006) (quoted with approval in *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007)).

In the sentence just prior to citing the *Kahn* case, the U.S. Supreme Court clearly stated that there has to be an apparent reason to combine the known elements in the manner claimed. The Office has the burden of making out a *prima facie* case of obviousness, i.e., by presenting objective factual evidence of a reason to combine the known elements in the manner claimed. The *KSR* decision did not lift that burden from the Office.

The articulated reasoning has to express a rationale explaining what would have led an ordinarily skilled artisan to combine selected features from each reference in a way that would have resulted in the claimed invention. See, *KSR Int'l Co. v. Teleflex, Inc.*, 127 S. Ct. 1727, 1741 (2007). Thus, the Supreme Court reaffirmed the fundamental principles set forth in the *Graham v. John Deere Co.* decision, cited and discussed above.

Claim 1, as amended, recites an external pressure type hollow fiber membrane module of an external pressure type having a membrane occupying rate set to between 0.3 to 0.6, comprising: a hollow fiber membrane bundle formed of a plurality of hollow fiber membranes, a cylindrical housing, and a nozzle for allowing a fluid to enter into and exit therefrom, wherein the hollow fiber membranes are adhesively fixedly adhered to each other and to the inner wall of the housing at ends of the hollow fiber membrane bundle and form a membrane chargeable region in the inner side of the adhesively-fixed ends; wherein a hollow part is opened in one side or both sides of adhesively-fixed ends; and wherein the nozzle for allowing the fluid to enter and exit therefrom is installed on a side face of the housing of at least one adhesively-fixed end at which the hollow part is opened; wherein a membrane-occupying rate in the housing is set at 0.3 to 0.6, and a ratio PB/PA of membrane-occupying rates is 0.50 or more but 0.95 or less when

each of PA and PB is defined as the membrane-occupying rate in a neighboring region (A) of the nozzle and a non-neighboring region (B) of the nozzle which includes all regions other than neighboring region (A) in the membrane chargeable region in the inner side of an adhesively-fixed end of the opened hollow part.

Claim 2, as amended, recites an external pressure type hollow fiber membrane module of an external pressure type having a membrane occupying rate set to between 0.3 to 0.6, comprising: a hollow fiber cartridge having a hollow fiber membrane bundle formed of a plurality of hollow fiber membranes, of which both end parts are adhesively-fixed and hollow parts in at least one end of adhesively-fixed ends are opened and form a membrane chargeable region in the inner side of the adhesively-fixed ends; and a cylindrical housing accommodating the cartridge and having a nozzle for allowing a fluid to enter and exit therefrom installed on at least one side face, in which the nozzle installed is fixed so as to be placed in the vicinity of the inner surface of an adhesively-fixed part in the opened hollow parts side in the hollow fiber membrane cartridge; wherein a membrane-occupying rate in the housing is set at 0.3 to 0.6, and a ratio PB/PA of membrane-occupying rates is 0.50 or more but 0.95 or less when each of PA and PB is defined as the membrane-occupying rate in a neighboring region (A) of the nozzle and a non-neighboring region (B) of the nozzle which includes all regions other than the neighboring region (A) in the membrane chargeable region in the inner side of an adhesively-fixed end of the opened hollow part .

Claim 11, as amended, recites an external pressure type hollow fiber membrane module of an external pressure type having a membrane occupying rate normally set to between 0.3 to 0.6, comprising: a cylindrical housing; a hollow fiber membrane bundle formed of a plurality of hollow fiber membranes located inside of the cylindrical housing; a nozzle for allowing a fluid to enter into and exit from the housing, located on a side wall of the cylindrical housing wherein the membrane bundle extends across the cylindrical housing and is separated in cross-section into two regions, a first region taking up at least one fourth of the cross-sectional area of the

membrane bundle located between a portion of the wall of the cylinder that extends about the nozzle to approximately the center of the cylinder, and a second region that extends from the first region to the side of the wall of the cylinder that is opposite to the side of the wall in which the nozzle is located, and wherein a ratio PB/PA of membrane-occupying rates is 0.50 or more but 0.95 or less when PA is defined as the membrane-occupying rate in the first region, and PB is defined as the membrane-occupying rate in the second region, and wherein the membrane occupying rate in the housing is between 0.3 to 0.6.

Claim 12 recites an external pressure type hollow fiber membrane module of an external pressure type having a membrane occupying rate normally set to between 0.3 to 0.6, comprising: a rod-shaped bundle of hollow fiber membranes formed of a plurality of hollow fiber membranes, a cylindrical housing, and a nozzle for allowing a fluid to enter into and exit from the housing, the hollow fiber membranes being fixedly adhered to each other and to the inner wall of the housing at ends of the hollow fiber membrane bundle; a hollow part opened in one side or both sides of adhesively-fixed ends of the hollow fiber membrane; and wherein the nozzle for allowing the fluid to enter and exit therefrom is installed on a side face of the housing of at least one adhesively-fixed end at which the hollow part is opened; wherein the rod-shaped bundle of hollow fiber membranes extends across the cylindrical housing and has a has a neighboring region (A) having a cross-sectional area that surrounds the nozzle and extends from the nozzle approximately half way to a side of the cylindrical housing opposite to the nozzle, and a non-neighboring region (B) of the nozzle which has a cross-sectional area that encompasses the cross-sectional area of the cylindrical housing other than that cross-sectional area encompassed by neighboring region (A), and wherein the membrane occupying rate in the housing is between 0.3 and 0.6.

Support for the specific membrane occupying rates added by this amendment is found, for example, in the application as originally filed. See, for example, paragraph [0005] of the specification of the published version of this Application, i.e., U.S. 2007/0039868.

Initially, Applicants respectfully submit that the module disclosed in Haworth (U. S.

Patent Re. 36,125) relates to a hollow fiber blood oxygenator having the packing fraction (which is referred to as "the membrane-occupying rate" in this application) of an excess of about 60% (see col. 1, line 62 to col. 2, line 12). In short, the hollow fiber bundle disclosed in Haworth relates to the module requiring a high membrane occupying rate of an excess of about 0.6, which is inherently different from the modules of the present invention requiring a low membrane-occupying rate.

With respect to claims 1, 2 and 12, Applicant respectfully submits that Haworth does not disclose an external pressure type hollow fiber membrane module having a membrane occupying rate set to between 0.3 to 0.6, as positively recited in the claims. In this regard, Applicant notes that this feature is positively recited in the claim preamble and in the body of the claim and gives life and meaning to the claims, and has to be given patentable weight. Applicant also notes that they disclose that the filters of the disclosed invention are of the external pressure type which have a membrane occupying rate normally set to between 0.3 and 0.6. Haworth clearly does not disclose an external pressure type of hollow fiber membrane module, as claimed.

Nor does Haworth disclose a neighboring region (A) having a cross-sectional area that extends substantially symmetrically about a line coincident with the longitudinal axis and substantially bisecting the cylindrical housing and extends from a side of the cylindrical housing adjacent to the nozzle a substantial distance from adjacent to the nozzle and toward the center of the cylinder, and a non-neighboring region (B) of the nozzle which has a cross-sectional area that extends from the neighboring region (A) up to a side face of the cylinder opposite to the side face of the cylinder where the nozzle is located among a membrane chargeable region in the inner side of the adhesively-fixed part, in an adhesively-fixed end in the vicinity of the nozzle.

Also, with respect to claim 11, Haworth does not disclose a rod-shaped hollow fiber membrane bundle that extends across the cylindrical housing, as claimed, but discloses a membrane bundle with an annular cross-sectional shape.

Further with respect to claim 11, Haworth does not disclose the membrane bundle is separated in cross-section into two regions, a first region taking up at least one fourth of the cross-sectional area of the membrane bundle located between a portion of the wall of the cylinder

that extends about the nozzle to approximately the center of the cylinder, and a second region that extends from the first region to the side of the wall of the cylinder that is opposite to the side of the wall in which the nozzle is located, and wherein a ratio PB/PA of membrane-occupying rates is 0.50 or more but 0.95 or less when PA is defined as the membrane-occupying rate in the first region, and PB is defined as the membrane-occupying rate in the second region.

Furthermore, with respect to all recited claims, Applicant also respectfully submits that, significantly, Haworth does not disclose an external pressure type hollow fiber membrane module, as claimed. In this regard, it is Applicant's understanding that the driving force for the movement of oxygen from one side of a membrane into the other side, which is in contact with blood that needs to be oxygenated is the difference between the partial pressures of the oxygen in the blood and on the other side of the membrane. In Haworth, it appears that the partial pressure of oxygen that is supplied to the oxygenator unit is greater than the partial pressure of oxygen in the blood that is supplied to the oxygenator unit, so that the oxygen will move from the inside of the microfibers to the blood that is on the outside of the microfiber (ref. col. 8, lines 8 to 14). See, in this regard, a four page article entitled, "Heparin-Coated Blood Oxygenators" with the following Internet citation: "http://biomed.brown.edu/Courses/BI108/2006-108websites/group01Heparin-coatedOxygen . . .," which describes how oxygenators like that of Haworth operate. A copy was attached to the Amendment filed on March 1, 2010, for the Examiner's convenience.

Applicant also notes that one of ordinary skill in the art readily understands what is meant by an external pressure type of filtration system. In this regard, Applicant respectfully directs the attention of the Examiner to U.S. Patent 6,331,248 to Taniguchi et al., which explains, (see col. 11, lines 45-54) the difference between an internal pressure filtration system and an external pressure filtration system. According to Taniguchi et al., in an internal pressure type of hollow fiber membrane, the raw water is fed to the hollow portion of the hollow fiber membrane and filtration is effected from the inner surface side to the outer surface side of the membrane, whereas in an external pressure filtration system, the raw water is fed from the outer surface to the inner side surface of the membrane.

Accordingly, Haworth cannot possibly disclose, suggest, or otherwise render obvious the claimed invention, which recites an external pressure type hollow fiber membrane module.

Thus, claims 1, 2, 11 and 12 as amended, are not unpatentable over Haworth.

Reconsideration and withdrawal of this rejection of claims 1, 2, 11 and 12 are respectfully requested.

Rejection Under 35 U.S.C. § 103

Claims 1-5 and 11-12 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent Application Publication 2002/0079260 to Boivin et al. ("Boivin") in view of Haworth. This rejection is respectfully traversed.

A complete discussion of the Examiner's rejection is set forth in the Office Action, and is not being repeated here.

Applicant respectfully submits that claims 1 and 2, as amended, patentably define over both Boivin and Haworth.

Boivin differs fundamentally from the claimed invention in that Boivin's bundle of fibers has annular zones of fibers of different density, the more densely packed fibers being on the outside annular regions of the bundle and the less densely fibers being located toward the center of the bundle. As shown in Fig. 5, for example, the density of the fibers peaks at the outside of the bundle and is minimal at the center of the bundle.

However, this is not what is claimed. In the claimed invention, the density of the fibers changes from a relative high density in region (A) that is a neighboring region to the side nozzle to a relatively low density in a region (B) that comprises all other regions than region (A).

Moreover, Haworth and Boivin are used for different purposes and have different operational configurations, Boivin's devices being limited to a rod-shaped cross-section and being used as blood dialyzers where the blood is injected via a side wall inlet and removed via another side wall outlet, whereas Haworth's device is limited to blood oxygenation devices utilizing annular cross-section fiber bundles to accommodate the oxygenating gas.

Moreover, the Office Action does not establish whether Boivin's device is an external

pressure type hollow fiber filter, and for reasons discussed above, Haworth's device is not an external pressure type hollow fiber filter. Accordingly, the conclusion that Boivin and Haworth are combinable because they are concerned with the field of varied packing fraction hollow fiber membranes is clearly undercut because it clearly overlooks the fact that the Office Action does not establish whether Boivin's device is an external pressure type hollow fiber filter, and for reasons discussed above, Haworth's device is not an external pressure type hollow fiber filter.

If Boivin's device is an internal pressure type filter, then both Boivin and Haworth are not relevant to the claims, and if Boivin is an external pressure type filter, then the Office Action fails to explain what Haworth's internal pressure type filter has to do with properly modifying Boivin's external pressure type filter.

Additionally, the varied packing ratio configurations of both references differ significantly and the Office Action fails to explain exactly how Haworth's varied packing ratio configurations can be applied to Boivin's concentric packing ratio configurations to arrive at the claimed invention. Instead, the Office Action merely speculates that the configurations of Haworth (which Applicant notes vary considerably) when applied to Boivin's concentric configuration will result in the claimed invention. Applicant respectfully disagrees with this speculative conclusion, especially where the result of the proposed modification of Boivin will completely change its concentric configuration to a linear gradient from one side of Boivin's hollow chamber to an opposite side thereof, which will destroy Boivin's preferred embodiment (shown in Fig. 5).

Thus, the Office Action does not satisfactorily establish that one of ordinary skill in the art would be properly motivated to turn to Haworth to modify Boivin, as suggested.

Furthermore, Applicant respectfully submits that neither Boivin nor Haworth discloses or suggests the claimed invention no matter how they are combined.

Accordingly, reconsideration and withdrawal of this rejection of claims 1-5 and 11 are respectfully requested.

PCL/RJW:kml

Claims 6 and 7 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Boivin in view of Haworth and further in view of JP 62-204804 to Misao ("Misao").

As noted above, Applicant respectfully submits that claims 1 and 2, from which claims 6 and 7 depend (in the alternative) is not rendered obvious by Boivin and Haworth. Moreover, Misao is not being applied to remedy the aforenoted deficiencies of the Boivin-Haworth reference combination with respect to claims 1 and 2. So, even if one of ordinary skill in the art were properly motivated to modify the Boivin-Haworth reference combination in view of Misao, as suggested, the so-modified version of Boivin-Haworth would not render obvious the claimed invention.

Accordingly, reconsideration and withdrawal of this rejection of claims 6 and 7 are respectfully requested.

Claim 8 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over Boivin in view of Haworth and further in view of U.S. patent 5,282,966 to Walker ("Walker").

As noted above, Applicant respectfully submits that claims 1 and 2, from which claim 8 depends (in the alternative) is not rendered obvious by Boivin and Haworth. Moreover, Walker is not being applied to remedy the aforenoted deficiencies of the Boivin-Haworth reference combination with respect to claims 1 and 2. So, even if one of ordinary skill in the art were properly motivated to modify the Boivin-Haworth reference combination in view of Walker, as suggested, the so-modified version of Boivin-Haworth would not render obvious the claimed invention.

Accordingly, reconsideration and withdrawal of this rejection of claim 8 are respectfully requested.

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicant therefore respectfully requests that the Examiner reconsider all presently outstanding rejections and that they be withdrawn. It is believed that a full and complete response has been made to the outstanding Office Action, and as such, the present application is in condition for allowance.

If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone Robert J. Webster, Registration No. 46, 472, at (703) 205-8000, in the Washington, D.C. area.

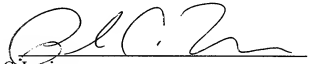
Prompt and favorable consideration of this Amendment is respectfully requested.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

Date: November 5, 2010

Respectfully submitted,

BIRCH, STEWART, KOLASCH & BIRCH, LLP

By: 

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